

LifeAssay Diagnostics Test-it™ PrCr Urinalysis Dipstick Test

Devices, Diagnostics, and Drugs to Address Women's Needs Product
Development Partnership (D₃AWN PDP)



Globally, approximately 300,000 women die in childbirth every year; more than half of these deaths occur in sub-Saharan Africa. These deaths are often preventable when health providers have access to necessary medical devices and medicines that enable higher-quality obstetric care.

Health need: Improved screening for preeclampsia during antenatal care

The risk that a pregnant woman will die from preeclampsia (PE) in a developing country is approximately 300 times greater than in developed countries.¹ Prevention of severe clinical complications due to PE, including maternal and newborn death, requires accurate and timely identification of women at high risk and their linkage to proper care. Protein in urine, or proteinuria, remains one of the key diagnostic indicators used to identify increased risk for PE. However, the current diagnostic tools that are available for proteinuria determination in developing countries have significant limitations. Protein-only urine dipsticks are widely used at the point of care,¹ but they have major limitations in terms of accuracy. Additionally, access to laboratory-based tests for improved proteinuria detection, such as the 24-hour urine test, remains very limited due to technical complexity and cost.

Potential health impact

A spot urine test can be used to determine the ratio of protein-to-creatinine (PrCr) and improve accuracy of proteinuria detection compared to protein-only measurement by adjusting for dilution of a patient's urine sample. Results using a PrCr measurement have previously shown close correlation with the current reference standard for proteinuria determination—a 24-hour urine-collection test.² Improving access to PrCr testing offers a potential near-term solution to improve proteinuria testing over available options, such as the protein-only test. This also has high potential to impact care and outcomes, particularly in low- and middle-income countries (LMIC) where most PE deaths occur and tools to improve diagnosis and care are most needed.



Photo: PATH/Patrick McKern

Technology solution

PATH and LifeAssay Diagnostics developed an innovative PrCr ratiometric urine dipstick test that improves accuracy of PE screening versus current tools, is able to be used at point of care, and costs pennies per test—comparable to the price of commonly available protein-only dipstick products. Results from the Test-it™ PrCr Urinalysis Dipstick Test are available in just 60 seconds with an easy-to-read colorimetric scale that supports rapid clinical decision-making for improved health outcomes.

Health system use case

Recent validation studies with the LifeAssay Diagnostics Test-it™ PrCr urinary dipstick test demonstrated improved accuracy of proteinuria screening versus protein-only dipsticks while maintaining similar low complexity and a comparable cost at pennies per test. Results of recent pilot studies to assess the usability and temperature stability of

The LifeAssay Diagnostics Test-it™ urinary dipstick test is accurate, easy to use, and inexpensive, making it appropriate for use during routine antenatal care services in low-resource areas.

the PrCr test also indicated potential suitability for use in peripheral antenatal care settings in LMIC.

In 2016, the usability of the LifeAssay Test-it™ PrCr Urinalysis Dipstick test prototype was evaluated in an antenatal care program in Kintampo, Ghana. Preliminary findings demonstrated ease of use of the test in target use settings. Under DFID funding, implementation research to support product optimization and introduction in Ghana and Kenya is being carried out.

Go-to-Market Plan (G2MP)

LifeAssay Diagnostics is ISO 9001 and ISO 13485 compliant and specializes in lateral flow and urinalysis tests. The LifeAssay Test-it™ PrCr Urinalysis Dipstick test product has received the CE (Conformité Européenne) mark and is registered in South Africa.

Final results from the evaluation of the LifeAssay Test-it™ PrCr Urinalysis Dipstick test prototype in an antenatal care program in Kintampo, Ghana will inform the next steps for development and introduction, build understanding of needs to optimize the use of the test, and generate additional data on the performance of the test in the field. Results of this study as well as planned implementation research will be used in outreach with key in-country stakeholders to familiarize them with the test and generate evidence to support introduction and procurement decisions.

Partners and support

Our project partners include Dr. James Roberts and The Global Pregnancy Collaboration, the Kintampo Health Research Center, and LifeAssay Diagnostics.

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D₃AWN PDP: Addressing the leading causes of maternal mortality with an innovative portfolio of products

The new, four-year Devices, Diagnostics, and Drugs to Address Women's Needs Product Development Partnership (D₃AWN PDP) is tapping into PATH's deep PDP expertise to develop and introduce a portfolio of devices, diagnostics, and drugs to prevent or manage preeclampsia/eclampsia (PE/E) and postpartum hemorrhage (PPH).

To address this critical health need, the D₃AWN PDP is advancing affordable, accessible, safe, and effective tools for sub-Saharan communities. Solutions include:

- heat-stable fast-dissolving tablet for PPH prevention; reusable,
- electricity-free infusion pump for the delivery of lifesaving nutrients, fluids, and medicines;
- balloon tamponade for the management of PPH;
- urinary dipstick test for improved diagnoses of PE/E.

These lifesaving technologies are being developed in partnership with research institutions, manufacturers, and companies in Africa, accelerated through PATH's product development process and introduced into key African markets.

References

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